IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

MELISSA M. ZIMMERMAN,	:	
	:	
Plaintiff,	:	
	:	
v.	:	
	:	
ABBOTT LABORATORIES, an Illinois Corporation, BASF AG, a Foreign Corporation, BASF CORPORATION, a Delaware Corporation, KNOLL PHARMACEUTICAL COMPANY, a New Jersey Corporation, GLAXOSMITHKLINE plc, a Foreign Corporation, and SMITHKLINE BEECHAM d/b/a GLAXOSMITHKLINE, a Pennsylvania Corporation,	:	C.A. No.
	:	JURY TRIAL DEMANDED
Defendants.	:	

COMPLAINT

I. PARTIES

1. Plaintiff Melissa M. Zimmerman is a resident of the State of Wisconsin, residing at 3331 Patti Drive, Apartment 3, Plover, Wisconsin 54467.

2. Defendant, Abbott Laboratories (hereinafter "Abbott") is an Illinois corporation with its principal place of business at 100 Abbott Park Road, Abbott Park, Illinois 60064-6400. Abbott manufactures, markets and distributes Meridia in over 70 countries.

3. Defendant BASF AG, ("BASF AG") is a German company with its principal place of business at 67056 Ludwigshafen, Germany. BASF AG is the

parent corporation for Knoll AG, BASF Pharma, and BASF Corporation. BASF AG has its principal place of business in the United States at 2000 Continental Drive North, Mount Olive, New Jersey 07828-1234.

4. Defendant BASF Corporation ("BASF"), is a Delaware Corporation with its principal place of business at 2000 Continental Drive North, Mount Olive, New Jersey 07828-1234. BASF Corporation is now a wholly-owned subsidiary of BASF AG and also conducts pharmaceutical research and development in the United States.

5. Defendant Knoll Pharmaceutical Company ("Knoll"), is a New Jersey corporation with its principle place of business located at 3000 Continental Drive North, Mount Olive, New Jersey 07828. Knoll has been a wholly-owned subsidiary of Abbott Laboratories since the first quarter of 2001. Prior to Abbott's acquisition, Knoll was a wholly-owned subsidiary of BASF AG, and served as BASF's United States pharmaceutical unit. Knoll Pharmaceutical Company develops and markets prescription drugs for obesity, including Meridia. Researchers in BASF's Pharmaceuticals Division in the United Kingdom and the United States developed sibutramine, the active ingredient in Meridia.

6. At all relevant times, Defendants Knoll and Abbott have been engaged in the business of manufacturing, marketing, distributing, promoting and/or selling the pharmaceutical drug sibutramine, sold under the trade name Meridia.

7. Defendant SmithKline Beecham Corporation is a Pennsylvania corporation with its principle place of business located at One Franklin Plaza, 200 North 16th Street, Philadelphia, Pennsylvania. SmithKline Beecham corporation is now a wholly-owned subsidiary of GlaxoSmithKline plc, and also conducts pharmaceutical research and development in the United States under the corporate fictitious name GlaxoSmithKline.

8. Defendant GlaxoSmithKline plc is a British corporation headquartered at Glaxo Wellcome House, Berkeley, Avenue, Greenford, Middlesex, England. GlaxoSmithKline plc has its principal place of business in the United States at One Franklin Plaza, 200 North 16th Street, Philadelphia, Pennsylvania. In December 2000, GlaxoSmithKline plc acquired Glaxo Wellcome plc and SmithKline Beecham plc, both British public limited companies. At all relevant times, GlaxoSmithKline was the holding company of SmithKline Beecham d/b/a GlaxoSmithKline, which was engaged in the business of marketing and distributing Meridia around the world in partnership with Abbott Laboratories and Knoll Pharmaceutical Company.

9. Hereinafter, GlaxoSmithKline plc, SmithKline Beecham Corporation d/b/a GlaxoSmithKline and SmithKline Beecham Corporation will be referred to collectively as "GlaxoSmithKline," unless otherwise specified.

10. GlaxoSmithKline entered into an agreement with Abbott to

distribute, market and sell Meridia. At all relevant times, GlaxoSmithKline and SmithKline Beecham conducted its marketing business from its headquarters in Philadelphia, Pennsylvania.

11. Defendants do business in the Commonwealth of Pennsylvania and in this judicial district.

II. JURISDICTION

12. This Court has jurisdiction over this civil action pursuant to 28 U.S.C. § 1332. There is complete diversity of citizenship between Plaintiff and Defendants, and the amount in controversy exceeds $150,000.00 exclusive of interest and costs.

III. FACTUAL BACKGROUND

13. In 1995, Defendant Knoll applied to the Food and Drug Administration (hereinafter "FDA") for approval of the oral prescription diet medication sibutramine hydrochloride monohydrate, to be marketed under the trade name "Meridia." Knoll sought permission to manufacture and market Meridia in 5, 10, 15 and 20 mg strength capsules.

14. According to patient information published by Abbott, Meridia contributes to a patient's weight loss by affecting appetite control centers in the brain. The drug is intended for people who are at least 25 pounds overweight (depending on height), or who have a body mass index ("BMI") of 27 or higher.

Meridia has a pharmacologic activity similar to amphetamines, including central nervous system stimulation and elevation of blood pressure. It has not been established that the action of this drug in treating obesity is primarily one of appetite suppression, and there may be other central nervous system actions and/or metabolic effects involved.

15. FDA personnel responsible for reviewing Knoll's application for approval of Meridia had concerns about the drug from the outset. On July 26, 1996, FDA officials met with representatives from Knoll to discuss their concerns regarding the approval of Meridia. The FDA asked the Knoll representatives if they had statistics on changes in plasma lipids in healthy obese patients as opposed to placebo-taking patients. Knoll representatives said they did not have this information. Knoll representatives explained that their information showed "favorable" trends in lipid profiles. They also said they believed that their information satisfied the FDA criteria for approval of this weight loss drug.

16. In reviewing the safety data, FDA personnel found a significant risk of cardiac arrhythmia, cerebrovascular accidents (strokes), thrombocytopenia, bleeding disorders, heart palpitations, increased systolic and diastolic blood pressure and tachycardia associated with the ingestion of Meridia. The increase in patient blood pressure was found in both patients with hypertension and in patients with blood pressure in normal range. Furthermore, the studies showed that Meridia caused increased blood pressure

whether or not the patient was taking anti-hypertensive medication.

17. The FDA officials expressed further concern over Meridia's link to blood pressure and cholesterol problems, as opposed to being independent risk factors. Knoll responded by stating that "some hypertension findings [in their data] are significant and some aren't." The FDA was having a hard time coming to a conclusion regarding the risks and benefits of Meridia based on the models Knoll presented. In fact, the FDA informed Knoll that so much of the data provided by Knoll was conflicting, which made it difficult to understand the effects of Meridia. As far as FDA officials were concerned, the alleged "favorable trends" that Knoll mentioned were not consistent findings.

18. The FDA informed Knoll that it was concerned that there was insufficient information explaining Meridia's effects on systolic blood pressure compared to diastolic blood pressure. Knoll agreed to undertake further research into this concern.

19. While discussing the findings of several studies on Meridia, the FDA stated that both the FDA and Knoll were analyzing the same data, but coming up with different conclusions. Therefore, the FDA stated that it had a "need for validation of analysis and adequate review time." Knoll acknowledged "further analysis may dictate labeling such as a black box warning."

20. One of the FDA medical officers who reviewed Knoll's data wrote that Meridia "has an unsatisfactory risk-benefit ratio and therefore this Reviewer recommends non-approval of the original submission."

21. On September 26, 1996, representatives from Knoll met with members of the FDA's Endocrinologic and Metabolic Drugs Advisory Committee to consider Knoll's application for Meridia. At the meeting, the FDA committee voted 5 to 4 that the benefits of Meridia do not outweigh the risks. The minutes of that meeting state:

> The Company forthrightly acknowledged that the drug causes systolic and diastolic increases in blood pressure …The limited and inconsistent benefits of the drug on lipid metabolism and diabetic patients were of concern to the Committee; limited the confidence that beneficial effects would offset the risks.

22. Despite the Endocrinologic and Metabolic Drugs Advisory Committee's cost-benefit analysis and concerns expressed by FDA reviewers, the FDA approved Knoll's application for Meridia in 5, 10 and 15 mg capsules in November 1997.

23. The Meridia marketing campaign began in early 1998 with direct-to-consumer advertisements such as television commercials and print ads in widely circulated periodicals, promotional literature to be placed in the offices of doctors and other healthcare providers, and other promotional materials provided to potential Meridia users. Defendants advertised Meridia as an effective weight control drug with minor side effects and a minimal risk of

adverse events, creating the impression that Meridia was safe for human use. These advertisements did not adequately address the adverse health events associated with the drug, including stroke, heart palpitations, increased heart rate and increased blood pressure.

24. In particular, in the materials produced by Defendants, Defendants falsely misrepresented the severity, frequency and nature of adverse health effects caused by Meridia and falsely represented that adequate testing had been conducted concerning Meridia.

25. Meridia's advertising campaign was successful; approximately 8.5 million people worldwide have used Meridia since its debut.

26. During the approximately 50 months the drug has been on the market, physicians and hospitals in the United States have reported to the FDA 397 serious adverse reactions associated with Meridia, including 29 deaths. The number of adverse reactions is usually estimated to be about tenfold higher than the number reported to the FDA due to intentional or unintentional failures to report adverse reactions to the agency.

27. For example, during a March 2002 FDA inspection of Abbott's plant in Abbott Park, Illinois, FDA investigators found evidence that Abbott withheld information from the FDA regarding eight Meridia-related deaths and other adverse reactions.

28. Adverse reactions to Meridia have also been reported throughout the world. For example, use of Meridia was suspended in Italy because of two

cardiovascular deaths associated with ingestion of the drug. In addition, 103 serious adverse reactions to Meridia have been reported in France and the United Kingdom.

29. Defendants knew or should have known that diet drugs such as sibutramine can cause adverse health effects ranging from shortness of breath, increased blood pressure and increased heart rate, and even death.

30. Plaintiff was prescribed and ingested 10 - 15 mg of Meridia per day from June 1999 through June 2000.

31. The product warnings in effect during the period when Plaintiff took Meridia were inadequate to alert prescribing physicians and consumer patients about the dangers of the drug.

32. Before Plaintiff began taking Meridia, Defendants knew that the drug was unsafe and had the potential and propensity to produce serious and/or life-threatening injuries and other damages. Notwithstanding their foregoing knowledge, Defendants failed to take appropriate action to make the drug safer or to adequately warn users and their physicians of Meridia's dangerous characteristics and defects.

33. Meridia caused serious injury to Plaintiff, including but not limited to hypertension, tachycardia, diastolic dysfunction and borderline concentric left ventricular hypertrophy.

34. Had Plaintiff known about the adverse reactions associated with Meridia, including increased heart rate and blood pressure, she would not have taken Meridia.

35. Defendants' conduct was outrageous, wanton and in reckless disregard for the health, safety and welfare of others, including Plaintiff.

COUNT I
STRICT PRODUCT LIABILITY (FAILURE TO WARN)

36. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth here.

37. Defendants are manufacturers, sellers, and/or suppliers of the drug Meridia.

38. Meridia was not accompanied by appropriate warnings regarding the risk of pulmonary or cardiovascular injuries posed by their ingestion. The warnings given by Defendants did not accurately reflect the risks, incidence, symptoms, scope or severity of such injuries.

39. Meridia, manufactured and/or supplied by Defendants, is defective due to Defendants' inadequate warnings and instructions.

40. The inadequate and defective warnings of Defendants have proximately caused Plaintiff to experience serious personal injuries, including high blood pressure, tachycardia and diastolic dysfunction.

COUNT II
STRICT PRODUCT LIABILITY (DEFECTIVE DESIGN)

41. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth here.

42. Meridia, as manufactured, sold and supplied by Defendants is defective in design or formulation and is unreasonably dangerous.

43. As a direct and proximate result of the defective and unreasonably dangerous condition of the drug, Plaintiff experienced serious personal injuries, including high blood pressure, tachycardia and diastolic dysfunction.

COUNT III
NEGLIGENCE

44. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth here.

45. Defendants had a duty to exercise reasonable care in the manufacture, sale and/or distribution of Meridia, including a duty to assure that the product did not cause users to suffer from unreasonable, dangerous side effects.

46. Defendants failed to exercise ordinary care in the manufacture, sale, testing, quality assurance, quality control, distribution and warnings of Meridia.

47. Defendants' negligence included without limitation:

a. failing to use due care in designing and manufacturing Meridia so as to avoid the aforementioned risks to individuals;

b. failing to accompany the product with proper warnings regarding all possible adverse side effects associated with the use of Meridia;

c. failing to conduct adequate pre-clinical and clinical testing and post-marketing surveillance to determine the safety of Meridia;

d. failing to provide adequate training and instruction to medical care providers for appropriate use of Meridia;

e. failing to warn that the risks associated with Meridia would exceed the risks of other comparable forms of weight loss.

48. Despite the fact that Defendants knew or should have known that Meridia caused unreasonable, dangerous side effects that many users would be unable to remedy by any means, Defendants continued to market Meridia to consumers, including Plaintiff, when there were safer alternative methods of weight loss.

49. Defendants knew or should have known that consumers and Plaintiff would foreseeably suffer serious personal injuries, including but not limited to increased blood pressure, tachycardia and diastolic dysfunction, as a result of Defendants' failure to exercise ordinary care as described above.

50. Defendants' negligence was a proximate cause of the serious personal injuries suffered by Plaintiff.

COUNT IV
BREACH OF IMPLIED WARRANTY

51. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth here.

52. At the time Defendants marketed, sold, and distributed the drug Meridia for use by Plaintiffs, Defendants knew of the use for which Meridia was intended and impliedly warranted those products to be of merchantable quality and safe and fit for such use.

53. Plaintiff and her physicians reasonably relied upon the skill and judgment of Defendants as to whether Meridia was of merchantable quality and safe and fit for their intended use.

54. In breach of the implied warranty given by Defendants, Meridia was not of merchantable quality or safe or fit for their intended use because the product was and is unreasonably dangerous and unfit for the ordinary purposes for which it was intended as described above.

55. As a direct and proximate result of the Defendants' breaches of implied warranty, Plaintiff suffered personal injury as previously described above.

WHEREFORE, Plaintiff demands compensatory damages against Defendants in excess of $150,000, punitive damages, plus all other relief that the Court deems to be appropriate based on the facts and applicable law.

Dated: May ___, 2002

Respectfully submitted,

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